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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/579,584	03/12/2007	Susan Bortolin	TMB-006	9399

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EXAMINER	
PANDE, SUCHIRA	
ART UNIT	**PAPER NUMBER**
1637	

NOTIFICATION DATE	DELIVERY MODE
09/03/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/579,584	BORTOLIN ET AL.	
	Examiner	Art Unit	
	SUCHIRA PANDE	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13 and 16-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-13, 16-22* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-9, drawn to a method.

Group II, claim(s) 10-13, 16-22, drawn to a product (kit and composition)

2. The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Kobler and Fieldhouse (WO 02/059355 A2 published 1 August 2002—provided by applicant in IDS) teach a kit (see page 34 line 38 where kit is taught) for use in detecting in a nucleic acid sample the presence or absence of a at least two variant nucleotides, said kit comprising a set of at least two tagged allele specific extension primers comprising a set of at least two tagged primers is taught. (See page 115 claim 75 where tagged primers are taught) wherein each tagged allele specific extension primer has a 3'-end hybridizing portion including a 3' terminal nucleotide being either complementary to a variant nucleotide or to the corresponding wild type nucleotide and a 5'-end tag portion complementary to a corresponding anti-tag sequence, (see whole document specially pages 55 and 56 example 2 where use of tags and anti tags and tagged primers that meet the above limitations are taught).

Humeny et al. (2001) Clinical Biochemistry 34 pages 531-536 teach use of allele specific extension primers to detect G20210A mutation in Factor II gene and Factor V Leiden allele two factors associated with thrombosis. (see page 531 abstract and page 532 section 2.3 Allele specific primer extension reactions along with the sequence of the allele specific extension primers is taught). Thus Humeny et al. teach at least two variant nucleotides (Factor V Leiden and Factor 2 G20210A associated with thrombosis). They also teach use of allele specific extension primers to detect mutations known to be associated with thrombosis.

Thus Humeny et al. teach wherein the at least two allele-specific extension primers comprise sequences associated Factor V Leiden and Factor 2 G20210A associated with thrombosis.

Thus prior art (Kobler & Fieldhouse along with Humeny et al.) teach use of at least two tagged allele specific extension primers. Hence all the components of the kit recited in claim 10 namely a kit for use in detecting in a nucleic acid sample the presence or absence of at least two variant nucleotides associated with thrombosis, said kit comprising a set of at least two tagged allele specific extension primers wherein each tagged allele specific extension primer has a 3'-end hybridizing portion including a 3' terminal nucleotide being either complementary to a variant nucleotide known to be associated with thrombosis or to the corresponding wild type nucleotide and a 5'-end tag portion complementary to a corresponding anti-tag sequence.

Claim 10 does not specify the primers of SEQ ID NO 1-12 consist of sequences of SEQ ID NO 1-12. Hence Examiner is interpreting the primers of SEQ ID NO 1-12

comprise sequence of SEQ ID NO 1-12. The nucleotides 1-24 of each of the SEQ IDs recited are the tag sequences taught by Kobler & Fieldhouse (see page 56 line 17 where 24 bp tag is taught attached to 5' end of the primers). Also see Example 2 page 69. The sequence of accession no ABS62162 referred to as analyte sorting tag sequence #634 shows a 100% match to the nt 1-24 of the instant SEQ ID NO.10. See alignment below

```
Nt 1-24 of SEQ ID 10
RESULT 1
ABS62162/c
ID   ABS62162 standard; DNA; 24 BP.
XX
AC   ABS62162;
DE   Analyte sorting tag sequence #634.
PN   WO200259355-A2.
XX
PD   01-AUG-2002.
PI   Kobler D,  Fieldhouse D;
PT   Polynucleotides comprising minimally cross-hybridizing nucleotide
PT   sequences, useful as tags or tag complements for use in a wide variety
of
PT   research, medical or industrial applications, e.g. in diagnostic assays
PT   or DNA sequencing.
XX
XX
SQ   Sequence 24 BP; 14 A; 0 C; 6 G; 4 T; 0 U; 0 Other;

  Query Match             100.0%;  Score 24;  DB 1;  Length 24;
  Best Local Similarity   100.0%;  Pred. No. 18;
  Matches   24;  Conservative    0;  Mismatches    0;  Indels    0;  Gaps
0;

Qy          1 AACTTTCTCTCTCTATTCTTATTT 24 Nt 1-24 of SEQ ID NO 10
              ||||||||||||||||||||||||
Db         24 AACTTTCTCTCTCTATTCTTATTT 1  tag #634
```

Further Venter et al. (US pat. 6,812,339 B1 with priority back to September 8, 2000) teach a sequence identified by SEQ ID 52930 that is 601 bp long. This sequence is associated with SNP of genes associated with human disease of which nt 592-575

show 100% match to the nt 25 to 42 of instant SEQ ID NO 10 claimed. See alignment below:

```
SQ   Sequence 601 BP; 211 A; 111 C; 93 G; 185 T; 0 U; 1 Other;

  Query Match             94.7%;  Score 18;  DB 2;  Length 601;
  Best Local Similarity   100.0%;  Pred. No. 7.3e+02;
  Matches   18;  Conservative    0;  Mismatches    0;  Indels    0;  Gaps
0;

Qy          1 GGCTGTATTTTTTTCCAG 18   nt 25-42 of SEQ ID NO 10
              ||||||||||||||||||
Db        592 GGCTGTATTTTTTTCCAG 575  SEQ ID 52930
```

Hence the components of kit of claim 10 was taught to one of ordinary skill by prior art. Therefore the kit of claim 10 does not share the same or corresponding special technical features of the method of group I invention. Hence unity of invention is lacking.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

4. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Restriction Subgroup

5. This application contains claims directed to the following patentably distinct Restriction Subgroups of the claimed invention. After election of one of the Groups above, Applicant is required to also elect a restriction subgroup. This is not a species election. Applicant will be required to cancel non-elected subject matter upon indication of allowable subject matter.

Each of the SEQ ID Nos recited comprise a patentably distinct subgroup.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed Subgroup consisting of a **single** set of primers (The primer set consists of 2 tagged allele specific primers identified by their SEQ ID NOs from SEQ ID 1-12 as required by claim 1—total of 2 primers. In addition the set also contains 2 pairs of amplification primers identified by their SEQ ID NOs from the group SEQ ID NO 13-24—as required by claim 5. ***A total of*** 2+ 4= ***6 primers*** need to be elected out of all the SEQ IDs recited) for prosecution on the merits to which the claims shall be restricted.

Applicant is advised that a reply to this requirement must include an identification of the restriction subgroup that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election. Should applicant traverse on the ground that the Restriction Subgroups are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the Restriction Subgroups to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Conclusion

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUCHIRA PANDE whose telephone number is (571)272-9052. The examiner can normally be reached on 8:30 am -5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Suchira Pande
Examiner
Art Unit 1637

/Suchira Pande/
Examiner, Art Unit 1637